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MPA100 OptiMelt Automated Melting Point Apparatus

Installation Qualification, Operation Qualification, and Performance Qualification Procedures

(Version 1.02, dated 06/08/06)

Company: _____

Location: _____

Instrument Model: MPA100 **Serial #:** _____

Comments: _____

SRS representative: _____ Customer: _____

Date: _____

Scope of Document

This Installation, Operation and Performance Qualification protocol will be performed on the SRS instrument described on the title page, located at the customer site which was identified on the title page, and specifically located at the building and room stated on the Protocol Approval page.

This protocol identifies the methods and documentation that will be used to evaluate this instrument for installation, operation and performance functions in accordance with the manufacturer's specifications.

On any page where a written entry is made, a direction is followed or data is gathered, that page must be signed and dated. This document may be used by the customer to perform the required procedures himself, or by a representative of SRS together with the customer. Should the customer choose to perform these procedures himself, a familiarity with the relevant operating and calibration procedures described in the MPA100 manual is necessary. All SRS representative signature lines should then be marked N/A (Not Applicable).

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Comments: _____

SRS representative: _____ Customer: _____

Date: _____

Protocol Approval (cont'd)

Protocol Acceptance/Approval by Customer

I, the undersigned, agree that the procedures described herein are applicable to the equipment defined on the title page of this document.

A per-page signoff area has been provided for those situations where an internal Standard Operating Procedure requires review and acceptance of each page of the delivered document. If this is not required, use the area to acknowledge deviations only. Acceptance of the entire document is considered to be complete when the certification of system qualifications is reviewed and signed on the Protocol Certification page of this document by the responsible parties.

Customer: _____
(Print Name and Title)

Signature: _____ **Date:** _____

Customer: _____
(Print Name and Title)

Signature: _____ **Date:** _____

Customer: _____
(Print Name and Title)

Signature: _____ **Date:** _____

Protocol Acceptance/Approval by Stanford Research Systems (SRS), if present

I, the undersigned, agree that the procedures described in this document assembled by Stanford Research System Technical Support Services, are appropriate for the equipment defined in this protocol and reflect the current Stanford Research Systems qualification procedure.

Authorized SRS Representative: _____
(Print Name and title)

Signature: _____ **Date:** _____

Comments: _____

SRS representative: _____ Customer: _____

Date: _____

Description of Typical Use

The MPA100 OptiMelt Automated Melting Point Apparatus is a bench-top instrument designed to measure melting point of samples. It relies on the capillary method supported by virtually all pharmacopeia procedures for melting point determinations.

Instrument Description

Model Number: MPA100

Serial Number: _____

Specifications

Operation

Temperature display	Melting point & Melting point range.
Temperature range	(Room temperature +10 °C) to 400 °C
Temperature resolution	0.1 °C
Ramp rate	0.1 °C to 20 °C per minute
Heat-up time	~10 minutes (50 °C to 350 °C)
Cool-down time	~10 minutes (350 °C to 50 °C)
Temperature accuracy	±0.3 °C (up to 100 °C) ±0.5 °C (up to 250 °C) ±0.8 °C (up to 400 °C)
Reproducibility	0.2 °C
Temperature sensor	Pt RTD (built-in)
Oven control	Closed-loop pid

General

Display	Back-lit, 5.8" (diagonal) touch screen LCD
Printer interface	RS-232 serial port. Support Epson & Citizen compatible dot matrix printers.
Computer interface	USB. All instrument measurements may be performed using the optional MeltView software.
Capillaries	
Dimensions	1.4 mm to 2.0 mm outside diameter, 100 mm length
Capacity	Up to 3 tubes simultaneously
Fill height	2 mm to 3 mm
Power	90 to 264 VAC, 47 to 63 Hz, 125 W
Operating temperature	0 °C to 40 °C, non-condensing.
Weight	9 lbs.
Dimensions	7.5"X10"X8.5" (WXHXL)

Comments: _____

SRS representative: _____ Customer: _____

Date: _____

Safety Instructions and Warnings

- **SAFETY PAYS!** Safety instructions must be strictly followed during all stages of installation, operation and service of this product. Failure to comply with these precautions and warnings violates the safety standards expected of users of this product, and may result in serious personal injury, including death, and significant property damage.
- The Operations Manual is a component of the product and must remain readily available to all laboratory personnel with access to the OptiMelt Melting Point System.
- If you have any doubts about how to use this product safely, contact Stanford Research Systems using the contact information provided in the manual.
- Do not use this product for any purpose other than its intended usage.
- Retain these safety and operating instructions for future reference.
- Identify and adhere to all warnings posted on the product and throughout the manual.
- The instruction manual should form the basis of any training requiring the use of this product.
- Wear protective garments such as lab coat and goggles at all times.
- Refer servicing to qualified personnel only.

Electrical Shock Risks

- It is your responsibility to install and operate this product in full conformance with local electrical codes. Consult an experienced electrician if necessary.
- If the power cord becomes damaged, replace it immediately.
- Dangerous voltages capable of causing injury are present during the operation of this product. Do not remove the covers while the unit is plugged into a live outlet.
- Do not use this product if it has unauthorized modifications. Unauthorized modifications may result in fire, electric shock and other hazards.
- Do not install substitute parts or perform any unauthorized modifications to this instrument.
- The line fuse is internal to the instrument and may not be serviced by the user.
- Always use an outlet which has a properly connected protective ground. Consult with an experienced electrician if necessary.
- GFCI (Ground Fault Circuit Interrupter) protected outlets are often available in laboratory environments, particularly in proximity to water sources. GFCI's are generally regarded as an important defense against electrocution. However, the use of a GFCI in conjunction with the OptiMelt must NOT be regarded as a substitute for proper grounding and careful connections. GFCI's must also be tested regularly to verify their functionality. Always consult an electrician when in doubt.
- Do not use accessories other than those recommended in the manual, because they may be incompatible with the MPA100 and cause a hazard.

Comments: _____

SRS representative: _____ Customer: _____

Date: _____

- Always turn off the power to the instrument before connecting any cable or accessory to the unit.
- Keep all electrical wiring on your laboratory benches neatly organized and in good working conditions. Label and color-code all high voltage cables. Inspect all HV wires periodically for problems as part of your safety checkups.
- Use tie downs and cable channels to hold electrical wiring in place (no loose wires).
- Keep all electronic instrumentation neatly organized, and remove unconnected cables, power supplies and connectors from your laboratory benches and shelves.
- Do not push objects of any kind into this product through openings as they may come in contact with dangerous voltage points or short out parts that could result in a fire or electric shock.
- Operation of this product with line voltages other than those accepted by the power supply can cause damage to the instrument and injury to personnel.

Burn Risks

- Observe and respect the “**HOT LID**” warning on the top surface of the product.
- Do not touch the heater block while hot.
- Check the temperature of the block before opening its compartment.

Explosion Risks

- This product is not compatible with application environments requiring explosion proof equipment, or compatibility with samples which may explode or ignite by heat, friction or spark.
- Do not use this product to analyze samples of unknown composition or contamination.

Product Placement Requirements

- Place this product on a stable, clean, level and even surface.
- Place the product away from water sources (i.e. faucets, safety showers, eyewashes, rain, etc.). Do not allow the product to become wet.
- No containers, chemicals or other appliances should be placed behind the product.
- Always operate the unit in its proper upright orientation. Do not operate the unit laying on its side.
- To prevent damage to the product and to ensure sufficient cooling in the electronic compartment, place the sidewalls of the unit at least 10 cm away from walls or any other objects.

Comments: _____

SRS representative: _____ Customer: _____

Date: _____

Documentation

The MPA100 OptiMelt Automated Melting Point Apparatus system includes the following documents:

Document	Present?
MPA100 Instruction Manual	
Certificate of Calibration	

There may be additional enclosures containing promotional or educational material.

Warranty and Maintenance Policy

Warranty

The MPA100 OptiMelt Automated Melting Point Apparatus system is fully guaranteed for one year from date of shipment against defects in materials and workmanship. It is certified against primary melting point standards traceable to WHO International Pharmacopoeia.

Should service be required during the warranty period there will be no charge for parts or service labor. Shipping charges for “return to factory” repairs are the responsibility of the customer.

For repair or service in _____, contact:

Maintenance

To assure many years of reliable operation, Stanford Research Systems recommends that C&CS (Calibration and Certification Service) be performed annually. This service consists of an inspection for temperature offset calibration, camera optical alignment, removal of broken capillaries, and cleaning the unit’s exterior. Your instrument is then calibrated and certified in writing to be performing within instrument specifications. This certification states that your instrument has been calibrated against standards which are traceable to the WHO International Pharmacopoeia.

Comments: _____

SRS representative: _____ Customer: _____

Date: _____

Installation Checklist and Qualification

Ordering Information:

Customer Order Number _____

Supplier Invoice Number _____

Check to be sure that all components are received and that there is no shipping damage. Note any missing parts and notify Stanford Research Systems, Inc. or local SRS agent immediately. Shipping damage must be reported to the carrier.

Inventory

Item	Quantity	Present?
MPA100 OptiMelt Melting Point Apparatus	1	
Power Cord	1	
Top Cover	1	
Glass Capillary Holders	2	
One Pack of Capillary Tubes	1	
MeltView Software CD	1	

Setup

Instruction	Completed?
Place the MPA100 OptiMelt on a stable, clean, level, even surface. Always operate the unit in its proper upright orientation. Place the sidewalls of the unit at least 10 cm away from walls or other objects.	
Insert the glass Capillary Holders into the two openings located on the top surface of the metal housing.	
Make sure that the AC power switch at the rear of the instrument is in the OFF position. Connect the power cord to the socket on the back panel of the instrument and plug it into the appropriate AC line.	

Comments: _____

SRS representative: _____ Customer: _____

Date: _____

Operation Checklist and Qualification

Verify that all functions operate normally as indicated.

Function	Operation	Completed?
Connect the power and optional printer (if purchased)	With the rear panel power switch in the off position, connect OptiMelt to a grounded outlet using the power cord provided. Connect the optional printer to a grounded AC outlet and connect the printer cable from the printer to the printer connector on the rear of OptiMelt.	
Turn on power	Turn the power switch on. Wait for the brief Power-On Self Test procedure to be executed. The Melt Screen is shown on the touch screen LCD, and the temperature should be displayed. The oven is off at this time.	
Touchscreen keypad	Perform touchscreen calibration. Select System menu, then Screen menu, then Align menu. Touch the "X" in each screen corner successively to complete the test.	
Configure the optional printer (if purchased)	Turn on the printer power switch. Configure the OptiMelt printer settings using the instructions in the MPA100 OptiMelt user manual.	
Prepare 3 chemical samples	Fill three capillaries to a 2 to 3 cm column height with a known chemical powder, keeping all three column heights equal. Tap the sealed end of each capillary on the table to compact the chemical.	
Enter the Start temperature at 5 °C below the expected melting point	The Start temperature is programmed by touching the Start button on the touchscreen LCD and entering a number using the displayed numeric keypad.	
Enter the Stop temperature at 5 °C above the expected melting point	The Stop temperature is programmed by touching the Stop button on the touchscreen LCD and entering a number using the displayed numeric keypad.	
Enter the ramp Rate at 1 °C/min	The ramp rate is programmed by touching the Rate/min button on the touchscreen LCD and entering a number using the displayed numeric keypad.	
Preheat the oven to the start temperature	Touch the Heat button on the Melt screen to preheat the oven to the start temperature.	
Insert the sample capillaries	Insert the capillary sample tubes into the OptiMelt and wait a few seconds for the temperature of the oven to stabilize.	
Initiate heating ramp	Touch the Start button on the Melt screen to initiate the temperature ramp.	
View the melt	During the heating ramp, view the melt through the observation window located on the front panel of OptiMelt.	
Recall the information	Touch the Report button to display a summary report for the melting point determination performed.	

Comments: _____

SRS representative: _____ Customer: _____

Date: _____

Performance Checklist and Qualification

Preparation and Acceptance Criteria

Sample Preparation	Acceptance Criteria								
Follow sample preparation instructions as specified in the Certified Reference Standards (CRS) O100MPS calibration kit.	1) Clear point for three capillaries must fall within ± 0.3 °C of each other for each CRS run. 2) MP range (clear point – onset point) must be less than 2 °C for each capillary (at 1°C/min ramp rate). 3) Temperature offset correction value of three CRSs should remain within limits given below. <table border="1" data-bbox="738 655 1242 800"> <thead> <tr> <th>Melting Point (°C)</th> <th>Accuracy (°C)</th> </tr> </thead> <tbody> <tr> <td><100</td> <td>± 0.3</td> </tr> <tr> <td>100 to 250</td> <td>± 0.5</td> </tr> <tr> <td>>250</td> <td>± 0.8</td> </tr> </tbody> </table>	Melting Point (°C)	Accuracy (°C)	<100	± 0.3	100 to 250	± 0.5	>250	± 0.8
Melting Point (°C)	Accuracy (°C)								
<100	± 0.3								
100 to 250	± 0.5								
>250	± 0.8								

Acceptability Test Procedure

Step	Completed?
Set the start temperature 5 °C below the certified clear point of the MPS. Preheat the oven to the selected temperature.	
For manual programming, set the ramping rate to 1 °C/min and the stop temperature 5 °C above the certified clear point of the CRS.	
Load three capillaries with a 2 to 3 mm column of one of the calibration standard chemicals. The height of the chemical in all three capillaries should be equal. Tap the closed end of each capillary on the table to make sure the chemicals are compacted at the bottom of the capillary. Insert the tubes into OptiMelt's sample slots.	
Start a melting point determination on the three identical samples.	
Using the Sample buttons on the touchscreen LCD display, record manual entries for the Onset and Clear point temperatures during the melt.	
Once the melt is completed and clear points have been detected, a report is generated.	
Table 1: Compare the visual results (manual entries for Clear point) for the three capillaries against each other. Table 2: Calculate the melting point ranges using manually recorded Onset and Clear temperature points. Table 3: Collect the averaged clear points obtained for the three CRSs, and calculate the temperature offset correction (TOC) for each CRS.	

Comments: _____

SRS representative: _____ Customer: _____

Date: _____

Performance Checklist and Qualification (cont'd)

Data and Acceptance Criterion

Table 1: The clear point for the three capillaries must fall within ± 0.3 °C of each other for each MPS run.

Name and Batch No.	MP Standard value	Clear Point Values obtained from OptiMelt Report			Criteria met?
		Left Capillary	Center Capillary	Right Capillary	

Table 2: MP range (clear point – onset point) must be less than 2 °C for each capillary (at 1 °C/min ramping rate).

Name and Batch No.	MP Standard Value	Values Obtained From OptiMelt Report				MP Range <2 °C Criteria Met?
		Capillary	Onset Point	Clear Point	MP Range	
		Left				
		Center				
		Right				
		Left				
		Center				
		Right				
		Left				
		Center				
		Right				

Comments: _____

SRS representative: _____ Customer: _____

Date: _____

Performance Checklist and Qualification (cont'd)

Table 3: Temperature offset correction values of the three MPS should remain within the limit given below.

Name and Batch No.	MP Standard Value (MP _{Std})	Clear Point Values Obtained From OptiMelt Report				TOC = MP _{Std} - MP _{Measured Average}	Accuracy Limit (from table pg.11)	Criteria Met?
		Left Capillary (A)	Center Capillary (B)	Right Capillary (C)	Measured Average (A+B+C)/3			

Any reading outside these limits may indicate a MPA100 problem. Contact the SRS technical sales department or your local SRS dealer/distributor with test results to determine the nature of the problem.

Comments: _____

SRS representative: _____ Customer: _____

Date: _____

Protocol Certification

Installation, Operation and Performance Qualification of the OptiMelt Automated Melting Point System

This Installation, Operation and Performance Qualification for the Stanford Research Systems instrument, Model MPA100, Serial Number _____, has been reviewed and that instrument was found to meet the necessary requirements to be used in the laboratory or facility identified in this document.

Authorized SRS Representative (if present):

Reviewed by (Print Name and Title)

Signature: _____ **Date:** _____

Authorized Customer Representative:

Reviewed by (Print Name and Title)

Signature: _____ **Date:** _____

Customer QA Representative: (if applicable)

Reviewed by (Print Name and Title)

Signature: _____ **Date:** _____

Comments: _____

SRS representative: _____ Customer: _____

Date: _____